DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2015

PuriCore Incorporated
Mr. Art Morse
Director of Quality Assurance and Regulatory Affairs
508 Lapp Road
Malvern, Pennsylvania 19355

Re: K141863
Trade/Device Name: PuriCore Wound Hydrogel Spray Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 11, 2015
Received: April 14, 2015

Dear Mr. Morse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141863

Device Name
PuriCore Wound Hydrogel Spray Dressing

Indications for Use *(Describe)*
Rx: Under the supervision of a healthcare professional, PuriCore Wound Hydrogel Spray Dressing is intended for management of wounds, including itch and pain relief, and to cleanse and moisten the wound bed. A moist wound and skin environment is beneficial to the healing process. It is intended for use on mechanically or surgically debrided wounds, Stage I-IV Pressure Ulcers, Partial and Full thickness Wounds, Diabetic Foot and Leg Ulcers, Post Surgical Wounds, First and Second Degree Burns, Grafted and Donor Sites, exit sites and intact skin, and various dermatoses, including contact dermatitis. It can be used during wound dressing changes to soften encrusted wound dressings.

OTC: PuriCore Wound Hydrogel Spray Dressing is intended for use to relieve itch and pain from minor skin irritations, minor lacerations, minor abrasions and minor burns, to cleanse and moisten the wound bed and for the management of minor cuts, exit sites and intact skin. It is also indicated for the management of minor irritation and pain from minor sunburn.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.
Submitter	PuriCore Inc., 508 Lapp Road Malvern, PA 19355
Contact Person	Art Morse; Director of Quality Assurance and Regulatory Affairs; PuriCore Inc. 508 Lapp Road, Malvern, PA 19355 484 321 2728 (O), 484 321 2704 (F), 610 306 2870 (C)
Date Prepared	May 8, 2015
Trade Names	Puricore Wound Hydrogel Spray Dressing
Common Name	Hydrogel Wound Dressing
Product Code	FRO (Dressing, Wound, Drug)
Predicate Devices	Predicates with substantially equivalent chemical composition, mechanical action, and labeling: • Primary Predicate: K123071: Vashe Skin Wound Hydrogel, January 24, 2013; • Secondary Predicates: – K101882: Prontosan Wound Gel, November 3, 2010 – K073547: Anasept Antimicrobial Skin and Wound Gel, April 23, 2008 – K093585: Microcyn Skin and Wound Hydrogel, March 8, 2010
Product Description	PuriCore Wound Hydrogel Spray Dressing is an aqueous hydrogel that aids in the removal of foreign objects such as dirt and debris from granulating wounds and forms a protective barrier that provides for a moist wound environment which loosens contaminated exudate, slough and other foreign materials within the wound bed. A moist wound environment is also supportive of the healing process by aiding autolytic debridement. PuriCore Wound Hydrogel Spray Dressing contains 0.050% Hypochlorous Acid that inhibits contamination within the hydrogel. The product is sprayable to aid / ease the application of the product. The device is presented as both a prescription product (that requires the physician to diagnose the disease state and prescribe the product) and for Over-The-Counter use. The device is offered in a 4.0oz bottle with a manual spray pump configuration. The product is packaged in a PET bottle and a polypropylene spay cap which enables the user to manually spray the product directly onto a wound or wound dressing. The device contains: Sodium Magnesium Fluorosilicate, Sodium Chloride, Water, Aqueous Phosphate Buffers, and Hypochlorous Acid (0.050%).
Intended Use Rx	Under the supervision of a healthcare professional, Puricore Wound Hydrogel Spray Dressing is intended for management of wounds, including itch and pain relief, and to cleanse and moisten the wound bed. A moist wound and skin environment is beneficial to the healing process. It is intended for use on mechanically or surgically debrided wounds, Stage I-IV Pressure Ulcers, Partial and Full thickness Wounds, Diabetic Foot and Leg Ulcers, Post Surgical Wounds, First and Second Degree Burns, Grafted and Donor Sites, exit sites and intact skin, and various dermatoses, including contact dermatitis. It can be used during wound dressing changes to soften encrusted wound dressings.
Intended Use OTC	PuriCore Wound Hydrogel Spray Dressing is intended for use to relieve itch and pain from minor skin irritations, minor lacerations, minor abrasions and minor burns, to cleanse and moisten the wound bed and for the management of minor cuts, exit sites and intact skin. It is also indicated for the management of minor irritation and pain from minor sunburn.

Summary of Technological Characteristics Compared to the Primary Predicate Devices	Puricore Wound Hydrogel Spray Dressing has the same or similar technical characteristics as the predicates listed above: • An aqueous based topical hydrogel which controls moisture and wound exudates. Hydrogel characteristics are imparted by an inert viscosity controlling agent. Maintains a moist wound environment that supports the wound healing process by encouraging autolytic debridement. The hydrogel barrier manages pain and itch by protecting the wound from contamination and irritation. • The Intended Use Statement utilizes the same indications as previously cleared under these predicate devices. The closure system for this product is substantially equivalent to the predicates as it is packaged in a PET bottle and a Polypropylene spray cap.
Substantial Equivalence - Effectiveness	Puricore Wound Hydrogel Spray Dressing utilizes the same fundamental scientific technology as the predicate device (K123071). Biocompatibility studies proved that the product is equivalent to the predicate products as it was determined safe under the worst case scenario of the highest specified concentration of available free chlorine and the lowest specified pH.
Pre-Clinical Testing	Pre-Clinical Testing included pH, Free Available Chlorine, Shelf Life, Chemical Stability, Antimicrobial Preservative Effectiveness, Agar Overlay Cytotoxicity, Primary Skin Irritation, and Guinea Pig Maximization Sensitization.
Conclusion:	Non clinical product testing has proven that Puricore Wound Hydrogel Spray Dressing is substantially equivalent to the predicate devices as the product has been subjected to in-vitro biocompatibility testing per ISO-10993-1 standards and Preservative Effectiveness testing. These results demonstrate that the product is as safe, as effective, and performs as well as or better than the legally marketed devices identified as the predicate devices listed above and in the Substantial Equivalence.